

**Department of Veterans Affairs
National Research Advisory Council (NRAC)
February 9, 2009
1722 Eye Street NW, Washington, DC
Garden Level Conference Room (GL 20)**

Meeting Summary

Members Present:

Richard Wenzel, MD, MSc, Chair
Col. Aaron Butler, USMC, Ret
Dudley Childress, PhD
Robert Kelch, MD

Members Absent:

Jeffrey Lieden, MD
David Korn, MD
Albert Reese, MD, PhD, MBA

OEF/OIF Subcommittee Consultants:

Joseph Czerniecki, MD
Hunter Peckham, MD
Stephen Waxman, MD, PhD

Guest Presenter:

Fran Weaver, PhD

VA Staff Present:

David Atkins, MD
Lynn Cates, MD
Gina Clemons
Kimberly Collins
Brenda Cuccherini, PhD
Seth Eisen, MD
Jay Freedman, PhD
William Goldberg, PhD
Peggy Hannon
Joel Kupersmith, MD
Timothy O'Leary, MD, PhD
Alex Orimaya, ScD
Ronald Przygodski, MD
Michael Selzer, MD, PhD

Guests:

Maj. Teresa Brininger, Ft. Detrich TATRC
Steve Heinog, American Association of American Medical Colleges
Beth Roy, Social and Scientific Systems, Inc.
Branka Seria, Social and Scientific Systems, Inc.

The meeting was called to order by Dr. Wenzel at 8:40 a.m. followed by introductions of all in attendance.

Report Update and Compliance Issues and Plans – Dr. Kupersmith

Dr. Kupersmith highlighted events since the last NRAC meeting to include an increase in research budget for FY 2009, change in role of Central Institutional Review Board (IRB), successful installation of electronic research applications, and challenges in research compliance and communications. Each topic was discussed throughout the course of the meeting.

Dr. Kupersmith reviewed a slide presentation entitled "Creating a Culture of Research Compliance in VA Medical Centers – Principles (for Thought)."

There were 9 Principles:

- Patient protection is part of clinical care
- Patient protection is an imperative
- All components of patient protection work together
- Everyone in the Medical Center has responsibility and is held accountable
- Human protections and compliance are part of everyday routine
- Culture that encourages self-policing and "good intent" reporting (non-punitive)
- Prevention as well as policing, anticipate the next battle and don't just fight the last one—take control, be proactive
- Make research compliance public, e.g., public display of research patient protection principles
- Implement change, e.g., post-conference events in Medical Centers

Dr. Kupersmith stated that "administrative culture" and "research culture" need to merge and find new ways of doing things.

2009 Research Local Accountability Meeting – Dr. Cates

Dr. Cates reported that the 2009 Office of Research and Development (ORD) Local Accountability for Research Meeting in January was the largest local accountability meeting to date. A total of 627 people attended including 11 Veteran Integrated Service network (VISN) Directors, 10 Chief Medical Officers, 113 Medical Center Directors (including a few who do not yet have research programs, but are interested in starting them), 106 Chiefs of Staff, 97 Associate Chief of Staff (ACOS)/Research and Development (R&D), 90 Administrative Officer (AO)/R&D, and 102 Research Compliance Officers (RCO). The goal of the meeting was to identify ways to improve local research programs, and there was a lot of focus on identifying respective responsibilities for research.

Evaluations indicated that the overall rating was 4.21 out of 5 for the various participants to be able to identify their research-related responsibilities.

Research Administrative Review – Dr. Ommaya

Dr. Ommaya stated that the Research Administrative Review is an initiative of ORD with 39 members from all aspects of the VA participating. The first report was issued December 15, 2008, and identified recommendations, e.g., R&D Committee policy that the Committee will review applications only if issues are raised or they are not reviewed by another committee; R&D needs a strategy to minimize variations in how protected time of clinician-researchers for research activities is administered in the Medical Centers; and the role of ACOSs and their involvement in leadership need to be addressed. Dr. Ommaya concluded with the idea that guidance needs to be provided on how to achieve a balance between the research mission and the clinical mission.

Electronic Review Update – Dr. Goldberg

Dr. Goldberg addressed the progress and changes in the electronic Research Administration (eRA) process as follows:

- Advantages of Transition to eRA
 - Electronic validations improve data
 - Images in proposal are consistent, clear and in color
 - Reduction in paper, storage space, scanning, printing and shipping
 - Electronic submission uses a common format and provides uniformity across services in use of forms, application process, and business practices
- NIH/VA recently transitioned from PureEdge to Adobe Reader as the forms manager for electronic applications
- 9 revised/new Requests for Applications (RFA) for submission to Biological and Laboratory R&D (BLR&D) and Clinical Science R&D (CSR&D) posted
- 80 VA Medical Centers have completed their institutional registrations in Grants.gov and eRA Commons
- VA Research Offices have submitted and we have verified the Commons ID (CID) for 2,493 VA investigators
- 466 applications were submitted and reviewed for the September deadline for BLR&D and CSR&D
- Final scores were entered at the November-December review meetings
- Summary statements were released to investigators via eRA Commons
- System does not make summary statements available to the Research Offices; they were faxed by staff
- I01 funding mechanism is now used
- Unresolved Issues
 - Technical problems delayed entering budget data and the generation of Notices of Intent to Award (anticipate resolution within next two weeks)
 - VA Medical Centers were notified manually of funding decisions by BLR&D and CSR&D

- Exceptionally pleased with help from the National Institutes of Health (NIH)
- Staff and field have bought into this system

Research Week Update – Ms. Gina Clemons

Ms. Clemons announced that National VA Research Week will convene May 3-9, 2009, with the theme, "Turning Hope into Reality." She stated that all VA medical centers are strongly encouraged to observe Research Week and to gear activities to Veterans. Posters will be distributed and other advertising items can be obtained through the Communications Office of Research and Development.

Ms. Clemons stated that the VA Central Office Research Week Kick-Off activities will be held April 28-May 1, 2009, on Capitol Hill and at the Washington, DC VA Medical Center. More than 300 participants are expected including Veterans, Veteran Service Officers (VSO), VA investigators, Congressional representatives, state officials, public speakers, members of the medical and scientific community, VA employees, and the media. One day each will be filled with activities devoted to--

- Emphasis on research (Cannon and Russell congressional buildings.);
- VA healthcare and benefits to the Veterans (Visitor Center.); and
- Health fair activities along with inspirational speakers and Veteran stories (Washington, DC VAMC).

ORD is working with Office of Public Affairs and Veteran Health Administration (VHA) Office of Communications to publicize upcoming events and arrange for video taping and daily press releases.

Nonprofit Research Corporations (NPCs) Update – Ms. Kimberly Collins

Ms. Collins stated that the Nonprofit Program Office (NPPO) consists of the administrator hired in September 2008 (herself), a staff assistant (hired in December 2008), and is actively recruiting an auditor/accountant to be hired within the next few months. Highlights of 2007 include:

- 2006 and 2007 annual reports are posted on the website
- There has been an increase in federal money and a decrease in private sector money
- There was approximately \$20 million in increased revenue between 2006 and 2007
- Total revenue in 2007 was \$250,453,983 (95.6% for research support, <1% for education, and 3.5% from general sources, e.g., interest income)
- There are 82 financially active facilities
- Of 82 audits performed in 2007, 5 NPCs were cited for having material weaknesses (weaknesses corrected for 4 of the 5 NPCs)
- NPPO database is being developed to increase oversight

- All NPCs will be reviewed in the next year (internal documents only) to get a snapshot of issues facing NPCs (Intended as a tool to reduce burden of scrutiny after an IG report)

Research Presentation – Frances M. Weaver, PhD

Dr. Weaver presented the results of a multi-site randomized trial study on deep brain stimulation (DBS) versus best medical therapy (BMT) for Parkinson's disease (PD) with 3-month and 6-month assessments. She stated the primary objectives were to compare patient motor function based on self-report diaries at 6 months following DBS or BMT, and to compare objective motor function, using the Unified Parkinson's Disease Rating Scale, for PD patients who underwent bilateral DBS or received BMT at 6 months. Out of 278 patients screened for eligibility, 255 were accepted and randomized for the trial: 134 assigned to receive BMT and 121 assigned to receive DBS. Dr. Weaver's conclusions were:

- DBS is superior to BMT in improving motor function and quality of life in a large cohort of PD patients.
- The on time gain (4.6 hours) is significantly larger than gains seen with adjunctive medications reported in other published studies (average +1-2 hours of on time).
- Quality of life improved significantly for DBS with little change in the BMT group.
- A large number of serious adverse events were experienced by DBS patients, including a 10% infection rate that was resolved within 6 months.
- A large number of general adverse events were related to disease progression and other chronic conditions.
- Older patients (≥ 70 years old) did almost as well as younger patients following DBS on motor function and quality of life.
- Physicians and patients should weigh the potential short- and long-term risks vs benefits of DBS in making decisions about surgical interventions for PD.

Dr. Weaver stated that her future plans are to analyze and report outcomes of randomized surgical targets: bilateral subthalamic nucleus vs globus pallidus interna based on motor function, quality of life, and adverse events; perform cost-effectiveness analysis; and conduct long-term follow-up of DBS patients.

Genomic Medicine Program Update – Dr. Przygodzki

Dr. Przygodzki gave preliminary results of a Spring 2008 survey of Veterans, who received healthcare at VA, which indicated that 83% of the 931 surveyed stated that a genomic medicine program should be done, and 71% said they would participate in such a program. He reported that the VA Boston Healthcare System conducted a pilot project to recruit and enroll 1,000 Veterans for the

purpose of genomic research. Twenty-three percent agreed to participate ("opt-in") as a reference cohort vs 6% to participate in UK Biobank procedure, and the Veterans preferred 90-minute visit time vs 360 minutes in UK Biobank. Dr. Przygodzki stated that the development of the Genomic Information System for Integrative Science (GenISIS), currently housed at the Boston MAVERIC, would provide a knowledge base to facilitate independent research projects and allow collaborative repurposing of data and results over the short-term. However, over the long-term, clinical care and research activities would enhance patient care. He indicated that there are several challenges to implementing such integrative technology because technologies are constantly evolving and data analysis and presentation needs vary.

Rehabilitation R&D Service Update – Dr. Selzer

Dr. Selzer stated that the mission of Rehabilitation R&D is to repair, replace, and restore function to the point that the Veteran can return to the workplace and participate in family and community activities. He addressed ways to promote research in social reintegration including solicitations for investigator-initiated research and Centers of Excellence/Research Enhancement Award Programs as well as vocational rehabilitation. Dr. Selzer stated that Rehabilitation R&D plans to have a 25-member panel of experts to provide training in research methodology for social reintegration research at some point during the fall of this year.

Health Services R&D Service Update – Dr. Eisen

Dr. Eisen stated that data from Veterans' Informatics, Information, & Computing Infrastructure (VINCI) will be accessible initially by Consortium for Healthcare Informatics Research (CHIR) investigators in February 2009 with subsequent access to all ORD services. He described a new initiative on Center for Research Professionalism. The aim is to identify and address factors that contribute to research professionalism and to develop a culture in which research professionalism thrives.

Quality Enhancement Research Initiative (QUERI) – Dr. Atkins

Dr. Atkins reported that QUERI had several accomplishments during FY2009: a very successful National Meeting in December 2008; QUERI is among the ORD initiatives to be highlighted for General Shinseki; growing number of VHA partners; and all 9 Centers received positive reviews and were re-funded for 1-3 years.

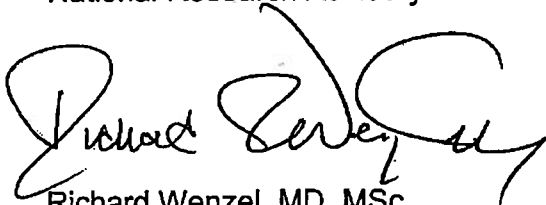
The next meeting is scheduled for May 11, 2009.

Meeting was adjourned at 2:30 p.m.

I hereby certify that, to the best of my knowledge, the foregoing minutes are an accurate and complete record of the substance of the meeting.



Jay A. Freedman, PhD
Designated Federal Officer
National Research Advisory Council



Richard Wenzel, MD, MSc
Chair
National Research Advisory Council

These minutes will be formally considered by the Council at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.